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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/578,806

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Deepak Gandhi

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EXAMINER

STEWART, JASON-DENNIS NEILKEN

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

06/14/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/578,806	Applicant(s) GANDHI ET AL.	
	Examiner JASON-DENNIS STEWART	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 18 and 40-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 18 and 40-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 January 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>23 February 2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The following is a Non-Final Office action in response to communications received on 1/15/2010. Claims 1 and 3 have been amended. Claims 4-8, 15, 16, and 19-39 have been cancelled. Claims 40-50 have been added. Therefore, Claims 1-3, 9-14, 17, 18, and 40-50 are currently pending and addressed below.

Oath/Declaration

The new oath/declaration filed 02/09/10 is accepted.

Drawings

1. The drawings were received on 01/15/10. These drawings are accepted.

Allowable Subject Matter

2. The indicated allowability of previously filed claims 5 and 6 is withdrawn in view of the newly discovered reference(s) to Brazzle et al. and Speidel. Rejections based on the newly cited reference(s) follow.

Response to Amendment

The amendments to the claims are sufficient of overcome the 35 U.S.C. 112, 2nd paragraph rejections of the previous Office action.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3, 10, 13, 14, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer 2003/0009215 in view of Brazzle et al. ("A Hysteresis-free platinum alloy flexure material for improved performance and reliability of MEMS devices").

5. Mayer discloses a stent made up of a platinum : iridium alloy having about 70%-80% platinum and 20%-30% iridium (paragraph 76). Mayer also discloses a 90% platinum - 10% nickel alloy and a platinum – tungsten alloy containing 5-15% tungsten. Mayer discloses the enhanced radiopacity of the stent because of these materials (abstract). Mayer further discloses that the stent may be balloon expandable or self-expandable as is well known in the art (paragraphs 5 and 28). Mayer also discloses the use of biocompatible coatings on the surface of the stent device (paragraph 27). Furthermore, Mayer discloses the use of a delivery catheter (paragraph 79) which encompasses balloon delivery catheters which are old and well known in the art for stent delivery as is there placement at the distal end of the catheter for deployment.

Mayer teaches the invention as claimed and as discussed above. However, Mayer does not disclose the use of an alloy made of about 75-80% platinum, 12-18% of rhodium, and 5-10% or ruthenium.

Brazzle teaches the use of Alloy 851 (a trade name for a platinum alloy having 79% platinum, 15% rhodium, and 6% ruthenium) in MEMS (microelectromechanical systems) as an ideal spring material.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent of Mayer with the alloy taught by Brazzle in order to gain desirable properties such as biocompatibility and extreme corrosion resistance as taught by Brazzle (abstract).

6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer 2003/0009215 in view of Brazzle et al. ("A Hysteresis-free platinum alloy flexure material for improved performance and reliability of MEMS devices"), as applied to Claim 1 above, and further in view of Alt 6,767,360.

7. Mayer in view of Brazzle teaches the invention as claimed and as discussed above. However, Mayer in view of Brazzle does not explicitly teach a stent having a sidewall thickness of less than 0.0035 inches.

Alt '360 teaches that a coronary stent has a sidewall thickness of 100 microns or less (col. 7, ll. 50-55).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent of Mayer in view of Brazzle with the sidewall width of Alt

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'360 since this is the typical strut width of a coronary stent as taught by Alt (col. 7, ll. 50-55).

8. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer 2003/0009215 in view of Brazzle et al. ("A Hysteresis-free platinum alloy flexure material for improved performance and reliability of MEMS devices"), as applied to Claim 10, further in view Alt 2004/0039438.

9. Mayer in view of Brazzle teaches the invention as claimed and as discussed above. However, Mayer in view of Brazzle does not teach a stent having iridium oxide or titanium nitrate coatings as well as therapeutic coatings.

Alt '438 teaches a stent having a titanium nitrate or iridium oxide coating as well as therapeutic coatings (abstract) to inhibit tissue irritation and to deliver therapeutics to a local site in the body.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent of Mayer in view of Brazzle with the coatings of Alt '438 in order to prevent tissue irritation and deliver drugs locally in the body.

10. Claims 40-42, 44, and 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer 2003/0009215 in view of Speidel ("Resistance to fatigue crack growth of the platinum metals").

11. Mayer teaches the invention as claimed and as discussed above. However, Mayer does not teach a stent made of an alloy that has a composition of about 65%-75% of platinum and 25-35% of rhodium.

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Speidel teaches that a 70% platinum / 30% rhodium as a useful platinum alloy because rhodium has a higher resistance to fatigue crack growth than most other metals under cyclical stress (abstract).

It would have been obvious to modify the stent of Mayer with the alloy disclosed in Speidel in order to resist fatigue crack growth under cyclical loading as taught by Speidel (abstract) since it is known that stents undergo cyclical stress *in vivo* and manufacturers would be motivated to use alloys that would resist cracking.

12. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer 2003/0009215 in view of Speidel ("Resistance to fatigue crack growth of the platinum metals") as applied to Claim 40, further in view of Alt 6,767,360.

13. Mayer in view of Speidel teaches the invention as claimed and as discussed above. However, Mayer in view of Speidel does not explicitly teach a stent having a sidewall thickness of less than 0.0035 inches.

Alt '360 teaches that a coronary stent has a sidewall thickness of 100 microns or less (col. 7, ll. 50-55).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent of Mayer in view of Speidel with the sidewall width of Alt '360 since this is the typical strut width of a coronary stent as taught by Alt (col. 7, ll. 50-55).

14. Claims 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer 2003/0009215 in view of Speidel ("Resistance to fatigue crack growth of the platinum metals") as applied to Claim 44, further in view Alt 2004/0039438.

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15. Mayer in view of Speidel teaches the invention as claimed and as discussed above. However, Mayer in view of Speidel does not teach a stent having iridium oxide or titanium nitrate coatings as well as therapeutic coatings.

Alt '438 teaches a stent having a titanium nitrate or iridium oxide coating as well as therapeutic coatings (abstract) to inhibit tissue irritation and to deliver therapeutics to a local site in the body.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent of Mayer in view of Speidel with the coatings of Alt '438 in order to prevent tissue irritation and deliver drugs locally in the body.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON-DENNIS STEWART whose telephone number is (571)270-3080. The examiner can normally be reached on M-F (alt Fridays off) 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/
Primary Examiner, Art Unit 3774

/Jason-Dennis Stewart/
Examiner, Art Unit 3738